PATENT

A

Docket No. 1135

Box Patent Application
Commissioner of Patents and Trademarks
Washington, D.C. 20231

NEW APPLICATION TRANSMITTAL

CERTIFICATION UNDER 37 CFR 1.10

I hereby certify that this New Application Transmittal and the documents referred to as enclosed therein are being deposited with the United States Postal Service on this date **June 7, 1999** in an envelope as "Express Mail Post Office to Addressee" Mailing Label Number **E1860717705 US** with proper postage affixed addressed to the: Commissioner of Patents and Trademarks, Washington, D.C. 20231.

FORREST L. COLLINS

(Type or print name of person mailing paper)

(Signature of person mailing paper)

Inventor(s): DR. VERNON WEN-HAU LIN, M.D.

WARNING: PATENT MUST BE APPLIED FOR IN THE NAME(S) OF ALL OF THE ACTUAL INVENTOR(S). 37 CFR 1.41(A) AND 1.53(B).

Title: TREATMENT OF EXCRETORY PROBLEMS

1. **Type of Application**

[X] Original

[] Continuation

[ ] Divisional

[ ] Continuation-in-part (CIP)

2. **Fee Calculation (37 CFR 1.16)**

☑ Regular application

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

CLAIMS AS FILED

	Number Filed	Number Extra	Rate	Basic Fee 37 CFR 1.16(a) $760.00
Total Claims (37 CFR 1.16(c))	25 - 20=	5 X	$18.00	$ 90.00
Independent Claims (37 CFR 1.16(b))	3 - 3=	0 X	$78.00	0$x
Multiple dependent claim(s), if any (37 CFR 1.16(d))			$760.00	$760.00

REDUCTION FOR SMALL ENTITY STATUS OF 50% PER ATTACHED CLAIM FOR SUCH.

[ ] Amendment canceling extra claims enclosed.

3. **Fee Payment Being Made and Authorization to Charge Fees**

[X] basic filing fee $ 425.00

[ ] recording assignment $__.__

4. **Papers Enclosed Which Are Required For Filing Date Under 37 CFR 1.53(b) (Regular) or 37 CFR 1.153 (Design) Application**

21	Pages of specification	1	Pages of Abstract
3	Pages of claims	4	Sheets of drawing

5. **Additional papers enclosed**

[] Preliminary Amendment

[ ] Information Disclosure Statement (37 CFR 1.98)

[ ] FORM PTO-1449

[X] SMALL ENTITY STATUS enclosed

[ ] Cited References

[ ] Other

6. **Declaration or oath**

[X] Executed

[ ] Unexecuted and enclosed

7. **Assignment**

[] An assignment of the invention to was previously filed.

[ ] A separate "Cover Sheet for Assignment (Document) Accompanying New Patent Application" is attached.

☑2 The Commissioner is hereby authorized to charge the following additional fees by this paper and during the entire pendency of this application to Account No. N/A

☑3 37 CFR 1.16(a)-(g)

☑4 37 CFR 1.17 (application processing fees)

☑5 credit any overpayment to Account No.

Total fees enclosed $ 425.00

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8. **Benefit of Prior U.S. Application(s) (35 USC 120)**

[] The new application being transmitted claims the benefit of prior U.S. application(s)

[X] This transmittal ends with this page.

CLAIM FOR SMALL ENTITY STATUS

Applicant: DR. VERNON WEN-HAU LIN, M.D. Docket No. 1135
Serial or Patent No.:
Filed or Issued:
Title: TREATMENT OF EXCRETORY PROBLEMS
VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS (37 CFR 1.9(f) and 1.27(b))-INDEPENDENT INVENTOR

As a below named inventor, I hereby declare that I qualify as an independent inventor as defined in 37 CFR 1.9(C) for purposes of paying reduced fees under SECTION 41(A) and (B) of Title 35, United States Code, to the Patent and Trademark Office with regard to the above-entitled invention which is described in:

[x] the specification filed herewith.

[ ] application serial no. filed

[ ] patent no. _____, issued_____.

I have not assigned, granted, conveyed or licensed and am under no obligation under contract or law to assign, grant, convey or license, any rights in the invention to any person who could not be classified as an independent inventor under 37 CFR 1.9(C) if that person had made the invention, or to any concern which would not qualify as a small business concern under 37 CFR 1.9(D) or a nonprofit organization under 37 CFR 1.9(E).

Each person, concern or organization to which I have assigned, granted, conveyed, or licensed or am under an obligation under contract or law to assign, grant, convey, or license any rights in the invention is listed below:

[x] no such person, concern, or organization
[] persons, concerns or organizations listed below

FULL NAME and ADDRESS

[] INDIVIDUAL [] SMALL BUSINESS CONCERN [] NONPROFIT ORGANIZATION

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(B)).

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under SECTION 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

DR. VERNON WEN-HAU LIN, M.D.	_____	_____
Name of inventor	Name of inventor	Name of inventor
Ven ~ Li	_____	_____
Signature	Signature	Signature
May 3, 1999	_____	_____
Date	Date	Date

TREATMENT OF EXCRETORY PROBLEMS

BY DR. VERNON WEN-HAU LIN, M.D.

CROSS REFERENCE TO RELATED APPLICATIONS

This application is a continuation in part of Serial Number 08/889, 767 filed July 8, 1997 which in turn is a continuation of United States Patent 5,833,595 issued November 10, 1998.

BACKGROUND OF THE INVENTION

1. Field of the invention. This invention deals with the treatment of excretory functions including urinary and defecation problems in mammals wherein the normal function is absent or severely impaired.

2. Description of the Art Practices.

It is known for most paraplegics that the bladder empties automatically and necessitates the wearing of an external collecting device. Reflex bladder contractions occur where the urethral sphincter may undergo an intermittent spastic contraction interrupting voiding and frequently leading to high bladder pressures. The foregoing situation is also accompanied by incomplete bladder emptying also known as detrusor sphincter-dyssynergia.

Typically, a patient whose sacral cord, or cauda equina is damaged often results in a flaccid bladder. Intermittent self-catheterization is often used by patients who are unable to completely void the bladder thus leaving a large residual amount of urine which predisposes the urinary tract to infections.

In addition to patients with spinal injuries, there is also the situation of surgical patients who need to void their bladder. The micturition process in patients under anesthesia may be necessary to prevent abnormally high bladder pressure. Such situation occurs where the patient is in need of urgent surgery, and normal procedures for bladder evacuation must be deferred. Another situation in which micturition may benefit from controlled response is in geriatric patients. In such situations it may be necessary to stimulate the patients bladder in a controlled setting to avoid bed-wetting.

Arnold, et al. discusses bladder function in an article entitled Sacral Anterior Root Stimulation of the Bladder in Paraplegics Aust. N.Z.J. Surg. 1986, 56, 119-124. The Arnold article treats the treatment of patients 12 month post-injury to allow the neurological status to become stable. Arnold describes the patient as being positioned in a prone situation and laminectomies of L 3 to S 2 (inclusive) are performed. The dura is then opened in the mid-line at the L 4 / L 5 level to S 2 with initial anatomical localization of the cauda equina nerves. Commencing unilaterally, the S 2 nerves are then identified and the motor and sensory components separated. Direct nerve stimulation is performed on the motor and sensory components with observation made of the detrusor and rectal pressures, pelvic floor and distal limb muscles.

The second stage of the operation in Arnold's patient is performed a week later. The patient is positioned in the lateral decubitus position and the coiled cables in the cutaneous pouch are exposed and lead subcutaneously to a radial-receiver unit which is placed in a subcutaneous pouch over the anterial lateral chest wall over ribs.

The transmitter coils are connected by a short cable to the signal generator control box which allows adjustment of the strength and frequency, shape and timing of the desired electro-stimulation. It is observed that voiding occurs in spurts after each burst of stimulation. The procedure of Arnold is difficult to put in practice with only two-thirds of the patients initially indicating a satisfactory response following surgery.

Li, et al, in Role of Electric Stimulation in Bladder Evacuation Following Spinal Cord Transection discusses bladder stimulation in The Journal of Urology vol. 147, 1429-1434. Li teaches neural stimulation as a potentially valuable therapeutic tool in the treatment of neurogenic bladder with detrusor areflexia.

Li discloses that the urinary bladder receives its innervation from 3 sources: Somatic, Sympathetic, and Para-Sympathetic. The Sympathetic innervation of the bladder is controlled by the hypogastric nerve; para-sympathetic impulses are carried by the pelvic nerve. The pudendal nerve which is derived from the sacral nerves supplies somatic innervation to the

striated musculature of the urethra. Li notes that the Somatic and Autonomic reflexes are lost in the event of a spinal cord lesion.

A review article was released by Madersvacher entitled Intravesical Electrical Stimulation for the Rehabilitation of the Neuropathic Bladder, Paraplegia 28 (1990) 349-352. Madersvacher stated that introvesical electro-stimulation dates back to 1878 which Saxtroph treated urinary retention by inserting a special catheter trans-uretherally into the bladder with a metal-electrode inside and with a neutral electrode placed suprapubically. The idea of electro-stimulation of the bladder to encourage functional micturition laid dormant until 1959 when Katona et al described the technique of intraluminal electro-therapy. Madersvacher also discusses trans-urethral electro-stimulation of the bladder being based on the activation of specific receptors in the bladder wall.

Nashold et al, in Electro Micturition, in Paraplegia Arch Surg Vol., Feb 1972. Nashold describes paraplegic patients who have undergone electrode implantation in the S 1 - S 2 region of the conus mudullaris. The electro-stimulation proceeded with a small battery-operated radio frequency stimulator and the receiver is stated to produce adequate emptying of the bladder every 3 to 4 hours. The male patients were stated to have required a sphincterotomy. Nashold states that the stimulation indexes employed at surgery and during the initial testing were biphasic square wave ranging from 100 to 500 microseconds in duration at various frequencies and voltages. Specific data concerning the parameters of Nashold indicate that the patient at home uses stimulation indexes of 15 to 30 cycles per second, 10 to 15 volts and 200 microsecond pulses for 30 to 60 seconds for emptying the bladder.

Urinary stimulation is discussed in an article entitled Sacral Anterior Root Stimulators for Bladder Control in Paraplegia by Brindley, et al. reported at Paraplegia 30 (1982) 365-381. Brindley discloses that patients whose bladders remain innervated by an isolated cord that is not severely damaged can achieve reflex micturition. However, many of the patients according to Brindley have large residual urine volumes and suffer from persistently or recurringly infected urine.

Brindley discusses an implant consisting of three parts. The Brindley article discusses the use of electrode "books" in which the sacral roots are trapped with three electrodes in each slot. Brindley discusses avoiding pressure through a thin urethral catheter during implant driven micturition after the implants had been in use for several months.

The discussion of chronically implanted electrodes for treatment of the spinal root is discussed in A Technique for Anodally Blocking Large Nerve Fibres Through Chronically Implanted Electrodes by Brindley, et al Journal of Neurology, Neural Surgery and Psychiatry 1980, 43, 1083-1090 (hereinafter Brindley II).

Mouchawar, in an article entitled Closed-Chest Cardiac Stimulation with a Pulsed Magnetic Field, Medical & Biological Engineering & Computing March 1992, page 162 discusses magnetic stimulator to generate intense, rapidly changing magnetic fields capable of stimulating nerves. Magnetic resonance systems utilizing coplanar coils to provide a pulsed magnetic field with an average of 12 kilojoules to achieve closed-chest magnetically induced ectopic beats. The Mouchawar article also describes the peak-induced electrical field for threshold stimulation at 213 V/m for a 571 microsecond damped sine wave pulse.

Voorhees III et al, in a technical note in the Journal of Clinical Engineering September/October 1990 page 407 article entitled Magnetically Induced Contraction of the Inspiratory Muscles in Dog discusses short-duration inspirations by discharging a capacitor bank into an excitation coil placed over the lower right chest. The Voorhees III article discusses utilizing the construction of the excitation coil as having 59 turns of 1/4 inch copper ribbon 0.0200 inches thick wound on a 3/4" diameter plastic rod where the outer diameter of the coil is 3.75" and the entire coil is potted in silicon rubber.

The inductanceper Voorhees III et al is 139 micro-H and the resistance is 0.084 ohms. The current was delivered to the coil from a 100-micro F capacitor bank. The resonant frequency of the system was 1350 Hz and the damping coefficient was 0.05.

Cadwell Laboratories, Inc. in Application Notes AP-2 Rev. 1 February 22, 1990, discusses high-speed magnetic stimulator characteristics. In a technical note by Bourland et al

in IFMBE, page 106-108 (March, 1990), entitled Transchest Magnetic (eddy-current) stimulation of the dog heart as reported in Med. & Biol. Eng. & Comput., 1990, 28, 196-198. The magnetic stimulator used by Bourland et al is described as a pulse generator with two coplanar coils connected in a series so that the current flows in a clock-wise direction in one coil and counter-clockwise in the other.

The Bourland et al coil and generator specifications were stated to be determined from computer simulations, and were optimized for minimal energy stored in the generator. The coils were described as 30-turn 106 Micro H Coil fabricated from 1/2" by 0.043" copper ribbon covered with a glass-epoxy insulation. The inter-diameter of each coil is 7.2 cm and the outer diameter is 16.5 cm. The magnetic stimulator and coils is a series RLC circuit, comprising a 682 micro F, 9900 V Capacitor, output switch (ignition) and 220 micro H inductor (combined value for both coils, including mutual inductance). The resistance of the Bourland device is stated to be 220 m ohms and a reverse-biased diode is connected across the 682 micro-capacitor to prevent reverse polarization.

A discussion of nerve stimulation was presented in IEE Transactions on Biomedical Engineering, Volume 37, NO. 6, 1990 under the heading of A Model of the Stimulation of a Nerve Fiber by Electromagnetic Induction by Roth et al.

Alexander, et al, in British Journal of Urology (1970), 42, 184-190 discusses electric pesky stimulation in a paper entitled Treatment of Urinary Incontinence by Electric Pessary A Report of 18 Patients.

In an article entitled Developing a More Focal Magnetic Stimulator Part I: Some Basic Principals by Cohen et al, as recorded in Journal of Clinical Neurophysiology, 8 (1); 102-111 (1991) magnetic stimulation is discussed generally. Similar disclosures are made by Yunokuchi et al in the Journal of Clinical Neurophysiology, 8 (1); 112-120 (1991) in an article entitled Developing a More Focal Magnetic Stimulator. Part II: Fabricating Coils and Measuring Induced Current Distributions.

The reader is also referred to Magnetic Stimulation in Clinical Neurophysiology edited by Sudhansu Chokroverty and published by Butterworths, Boston, London, Singapore, Sydney, Toronto, and Wellington Chapter 3 pages 17 through 32, pages showing Figures 7-18; 14-1; 17-4; 17-10, 18-3 and 18-4.

Further reference is made to Magnetic Brain Stimulation With a Double Coil: The importance of Coil Orientation by Mills et al. published in Electroencephalography and Clinical Neurophysiology, 85 (1992) pages 17-21. Reference is also made to a publication entitled the Effects of Coil Design on Delivery of Focal Magnetic Stimulation-Technical Considerations Cohen et al. Electroencephalography and Clinical Neurophysiology, 75 (1990) pages 350-357.

Further reading on the subject of magnetic studies of mammals is found in Brodak et al. Magnetic Stimulation of Sacral Roots Neurology and Urodynamics 12: pages 533-540 (1993) and in Motor Evoked Potentials From the Bladder on Magnetic Stimulation of the Cauda Equina: New Techniques for Investigation of Autonomic Bladder Innervation published in the Journal of Urology 147: pages 658-661 (1992).

A summary of the results of the magnetic stimulation presented in this patent was made on October 8, 1993 at the annual meeting of the AAEM Annual Meeting under the heading of High Frequency Magnetic Stimulation of the Inspiratory Muscles. A second presentation to the AAEM Annual Meeting on October 8, 1993 concerned Magnetic Stimulation of the Bladder in Dogs.

To the extent that the foregoing references are relevant to the present invention, they are herein specifically incorporated by reference. Where temperatures are given, they are in degrees C unless otherwise indicated. Pressure measurements are reported with reference to the reading at pubic symphysis as zero. Percentages and ratios given herein are by weight unless otherwise indicated. Measurements herein are stated in degrees of approximation thereby where appropriate the word "about" may be indicated before any measurement.

SUMMARY OF THE INVENTION

The present invention is directed to a method for treating a mammalian subject to regulate the excretory function including the steps of exposing the subject to sufficient electro-magnetic induction for a sufficient period of time to induce the excretory function.

The present invention also provides a method for treating a mammalian subject to regulate the urinary function including the steps of exposing the subject to sufficient electro-magnetic induction for a sufficient period of time to induce the excretory function wherein the field strength maximum is less than 5.0 Tesla, and having a focus of the electro-magnetic induction including that portion of the anatomy of the mammalian subject between the L 1 and S 5 vertebrae, and provided further that the pressure of the urinary bladder is measured prior to and/or during the electro-magnetic induction.

The present invention describes a method for treating a mammalian subject to reduce colonic transit time thereby regulating the excretory function including the steps of exposing the subject to sufficient electro-magnetic induction for a sufficient period of time to reduce colonic transit time and to induce the excretory function.

The present invention further describes a method for treating a mammalian subject to regulate the bowel function including the steps of exposing the subject to sufficient electro-magnetic induction for a sufficient period of time to reduce the colonic transit time and to induce the bowel function wherein the field strength maximum of the electro-magnetic induction is less than 5.0 Tesla, and having a focus of the electro-magnetic induction including that portion of the anatomy of the mammalian subject between the L 1 and S 5 vertebrae.

The present invention also describes a method for treating a mammalian subject to reduce gastrointestinal transit time thereby regulating the bowel function including the steps of exposing the subject to sufficient electro-magnetic induction for a sufficient period of time to reduce gastrointestinal transit time and to induce the excretory function.

DETAILED DESCRIPTION OF THE DRAWINGS

Figure 1 is a graph of the magnetic field at the center of a 70-mm mean diameter stimulation coil.

Figure 2 shows current focusing at a vertebral foramen.

Figure 3 shows a flow chart for determining the protocol to be used on a selected subject.

Figure 4 shows a male subject with anterior placement of the magnetic coil with various systemic functions being measured.

Figure 5 shows the simulation of a mammalian bladder and urethra both of which are monitored for baseline and electro-magnetically induced pressure.

Figure 6 shows the magnetic stimulator (source of electro-magnetic induction) in relation to the sacral nerves of a subject.

With more particular reference to the drawings the following is set forth. Figure 1 is self explanatory showing the relationship of a magnetic field at the center of a 70-mm mean diameter stimulation coil such as may be employed in the present invention.

Figure 2 shows magnetic current 1 focusing at a vertebral foramen 2 (orifice in the bony structure of the vertebra 3).

Figure 3 is a flow chart for determining the protocol to be used on a selected subject depending upon whether transabdominal and supine, or sacral and prone electro-magnetic induction stimulation is desired.

Figure 4 shows a male 10 subject with anterior placement of the magnetic coil 11 with a electro-magnetic stimulation provided by 12 a high frequency magnetic stimulator driven by a

computer 13 with monitor 14 and printer 15. Bladder, rectal and urethral pressure sensing devices are shown jointly as 16 and are connected to the computer 13 for monitoring, recording and feedback for measuring each function and changing the level, duration, and interval between each electro-magnetic stimulation.

Figure 5 shows the simulation of a mammalian bladder 20 and urethra both of which are monitored for baseline and electro-magnetically induced pressure by a bladder pressure catheter 21 and a urethral pressure catheter 22 both of which feed data to computer 13 (not shown).

Figure 6 shows the magnetic stimulator coil 11 (source of electro-magnetic induction) in relation to the sacral nerves 30 of a subject. Each of the sacral nerves is also separately noted by number in accordance with accepted practice.

DETAILED DESCRIPTION OF THE INVENTION

As previously discussed the present invention is concerned with excretory functions. In particular, the excretory functions of mammals are primarily urination (micturition) and defecation. In this patent, the term mammals includes all mammals, particularly those which are land-dwelling, and includes humans.

In mammals, where there has been a spinal cord injury, the resulting paralysis ordinarily extends beyond the point of the injury to the extremities. In the case of the urinary function, the bladder must typically be catheterized. That is, in the absence of sufficient nerve activity to stimulate the muscles surrounding the bladder, there is no proper bladder function.

The defecation function in mammals is somewhat less sensitive to spinal injury, as the vagus nerve supplies the excitatory parasympathetic activities from the esophagus to the mid-transverse colon. With proper diet and bowel care, defecation may occur.

In either the case of urination or defecation, there is a need for nerve function below the point of the injury to void urine and feces. In addition to nerve function the bladder it self being regulated by smooth muscle tissue may be reflexive, hyper reflexive or flaccid. The method of treatment described herein is to a greater or lesser extent useful in each of the aforementioned bladder states, however, as a practical matter the hyper reflexive or flaccid states will be the primary focus of the present invention.

Currently, hospitals periodically catheterize bladder-impaired patients. The process is costly and time-consuming, often resulting in additional trauma to the subject. Assisted defecation must be done with the process of enema or electrical stimulation of the bowel. The limited diet of a subject, the discomfort of constant enema or electrical stimulation often results in the patient giving up the will to live.

As previously discussed the invention deals with a non-physically invasive method to stimulate the urinary function and defecation function. The equipment utilized for the functional magnetic stimulation (electro-magnetic induction) of the excretory function is conveniently

available as a Cadwell HS M E S-10 Magnetic Stimulator 12 which is available from Cadwell Laboratories, Inc. 909 N. Kellogg Street, Kennewick, Washington 99336.

In any event, any suitable magnetic stimulation device may be utilized in the present invention. The general parameters for treating a mammalian subject are to expose the subject to a field strength between 1 Hertz and 150 hertz, preferably 3 Hertz to 100 Hertz and more preferably 10 Hertz to 40 Hertz. The duration of the stimulation provided is typically from 0.5 to 30 seconds, often 0.75 to 15 seconds and most preferably from 1 second to 8 seconds.

To approximate normal bladder and bowel function, the electro-magnetic induction is employed in repeated intervals from 0.5 to 20 seconds, typically 1 second to 15 seconds and most preferably 3 seconds to 12 seconds. The total number of the electro-magnetic induction cycles for urination stimulation are typically from 1 to 300, typically 2 to 250, and often 5 to 200. Desirably, the micturition will result in at least 100 milliliters, preferably at least 200 milliliters, and most preferably at least 250 milliliters of urine being voided during each episode of cycles of electro-magnetic induction, e. g. each series of treatments of the subject.

The electro-magnetic induction may be varied depending upon the patient response between each interval. Stated otherwise, insufficient response in the bowel or bladder will usually require slightly greater amounts of electro-magnetic induction in each interval until the optimum has been achieved. Often, the bowel function will require greater stimulation than the urinary function.

As later discussed, the bladder of injured patients may become dangerously full between voiding. A further aspect of the invention is the monitoring of the bladder to prevent damage thereto or to the urethra. For the moment, it is safe to say that the history of the treatment of each subject may be conveniently recorded electronically with the information fed into a computer so that each patients' profile is set for optimal elimination of urine and/or feces. Once the bladder and/or urethra and/or bowel profiles (particularly pressure) have been observed the catheterization such as for pressure measurements may be discontinued or monitored only intermittently thus causing less stress and pain to the subject.

As the bladder is typically much more sensitive to stimulation and the risk of injury it will typically be observed that it is more effective to stimulate for urinary function and thereafter increasing the stimulation for bowel function. However, there is no particular difficulty in utilizing both bowel and urinary function stimulation at the same time. Of course, where there may be any subject discomfort, the appropriate electro-magnetic induction may be utilized to only induce the desired excretory function.

The subject's behavior under stimulation may be aided by utilizing well known medical devices such as X-ray and ultra sound to determine the degree of success in the electro-magnetic induction of the excretory system. Typically, the entire bladder will not need to be completely voided, but will only be voided to the extent necessary to approximate a normal excretory function.

The location of the electro-magnetic induction is such that the coil will be placed directly upon the subject, up to a distance of not more than 0.1 meter, more preferably less than 1 cm or 0.5 cm from the surface of the subject. As there is a linear effect to the electro-magnetic radiation, it is desired that the coils be placed relatively close to the subject to accomplish several purposes.

First, by placing the coil close to the subject there will be little over-spray of the electro-magnetic radiation with the avoidance of stimulating other functions, such as respiration or cardiac function. Secondly, by placing the coils relatively close to the subject, the differences in signal strength of the electro-magnetic radiation will be minimized.

Lastly, the patient profile may be adjusted for the distance from the subject during the electro-magnetic induction. In some situations, the subject may have a sensitivity to having the coils placed directly upon the body which may be either of a physiological or psychological nature. Thus, by avoiding intimate contact with the subject, some degree of comfort may be obtained by the subject.

The area of the subject to be stimulated is typically in the lumbosacral region between the L 1 and S 5 vertebrae. Conveniently, the electro-magnetic induction is addressed to the area

between the L 4 and S 3 vertebrae. The subject may conveniently be either in the supine or the prone position. It is expected that with suitable experimentation a normal bowel function, while seated on the toilet may be possible.

The urinary function upon electro-magnetic induction will typically increase the bladder pressure to from 10 to 150 centimeters of water. As previously discussed the pressure of the urinary bladder may be measured in the subject before, during and after the electro-magnetic induction is initiated. A baseline may be obtained for the patient by utilizing a Dantec 5000 Urodynamic Investigation System.

A further variable in the present invention is the avoidance inducing urethra pressure with the electro-magnetic induction substantially greater than the bladder pressure which is induced.. That is, it is possible to stimulate both the bladder and the urethra substantially simultaneously such that micturition does not occur. Of course, if the bladder pressure is too great harm may occur to the subject when micturition does not occur. Thus it is desirable to monitor both the bladder and urethra pressure to maintain a differential when the electro-magnetic induction is occurring such that no harm occurs to the either urinary system. Typically, the induced pressure of the bladder should be greater than that of the urethra by a factor of preferably at least 50 %, preferably at least 40% and even greater than 20 %.

Conveniently, the mammalian subject is exposed to a field strength maximum of less than 3.0 Tesla. Conveniently the field strength maximum is less than 5.0 Tesla. The electro-magnetic induction device is typically operated between 50% and 100% of the maximum power, conveniently 60% to 80% of the maximum power. The maximum radiation strength per cycle of the electro-magnetic induction is maintained at less than about 50 microcurie per pulse.

The following is an exemplification of the present invention:

EXAMPLE I

A laboratory dog is stimulated utilizing a 9 centimeter coil placed firmly at the supra pubic region. A 4 second train of 20 Hz magnetic stimulation at 70% output is utilized. Peak bladder pressure in the animal is observed at 114 centimeters water of which 24 centimeters of water was due to a detrusor contraction.

The animal is observed to both urinate and defecate during the procedure.

EXAMPLE II

The following example is conducted on two human volunteer patients which were paraplegic at the T-7 location.

One patient was treated by placing the magnetic coil at the suprapubic region in the supine position and the second patient was treated in the lumbar position while in the prone position. In both cases the magnetic coil was placed directly on the patient.

The first patient demonstrates spontaneous uninhibited contractions of the bladder at approximately 110 milliliters of water filling in a routine water cystometry. The treatment level is a 3-second Hz stimulation at 70% power output. The peak bladder pressure increases from 20 centimeters at the baseline to 34 centimeters of water while the rectal pressure increases from 45 to 57 centimeters of water.

While lying prone, and applying the same stimulation to the lumbar region, the bladder pressure increases from 20 to 82 centimeters of water, and the rectal pressure increases from 46 to 104 centimeters water. By repetitively stimulating the lumbosacral region it is observed that spontaneous defecation occurs.

The second paraplegic patient demonstrated a flaccid bladder at 800 millimeters of fluid filling in the water cystometry. The second patient was placed in a supine position and the bladder filled at approximately 500 milliliters of fluid. The magnetic coil was placed at the suprapubic region and a three second train of 30 Hz magnetic stimulation with 70% power output is employed.

It is observed that the peak bladder pressure increases from 24 at baseline 265 centimeters water. The rectal pressure in the second patient increases from 32 to 56 centimeters water. When lying prone, and applying the same stimulation to the lumbar region, the second patient's bladder pressure increases from 32 to 77 centimeters water, and the rectal pressure increases from 23 to 48 centimeters water. Both urination and defecation occurred by repetitively stimulating the lumbar region.

EXAMPLE III

Each patient had a complete history and physical examination, which included a digital rectal examination and simple anoscopy to check for trauma or lesions of the anorectal verge using a disposable 3 inch anoscope, also included examination checking for the presence or absence of the bulbocavernosus reflex (BCR). Each patient emptied his bowel and bladder before the initiation of the study protocol. A BCR latency study was performed by stimulating the dorsal nerve of the penis with ring electrodes while recording potentials in the anal sphincter, by placing a 25 mm 30 gauge EMG needle at a site 1 cm posterior to the anal orifice to a depth of approximately 20 mm. A silver-plated surface electrode was placed nearby as reference electrode. A standard Nicolet Viking or Cadwell Excel electromyography machine was used for the above measurement ().

The patient was placed in the lateral decubitus position for the rectodynamic study. A multi-lumen anorectal balloon catheter was placed in the rectum and anal sphincter. A 15-minute period after insertion of the catheters was held to establish a quiet, baseline level of anorectal pressure activity. The anorectodynamic study was performed with monitoring of the rectal and anal pressures and the striated anal sphincter EMG while a rectal bag was gradually filled with water. The rectal inhibitory reflex was also determined first by anorectal pressure changes induced by fast infusion of air into the rectum (30 ml, 45 ml, and 60 ml), and then followed by gradually filling a plastic bag within the rectum while observing the anal relaxation. A Synetics Medical PC Polygraf VIII and Andorfer Medical Infusion System were used for the anorectal reflex measurement, and a Dantec 5000 Urodynamic Investigation System was used for the anorectodynamic study.

A Cadwell high speed, MES-lO magnetic stimulator and a standard, 85 mm mean diameter magnetic coil is used. This stimulator was capable of generating a maximum field strength of 2.2 Tesla, at the center of the coil. A personal computer with an interactive program written specifically for activating the stimulator was used to control the frequency and length of stimulation.

The patient was placed in decubitus position for functional magnetic stimulation of

the sacral nerves. Multi-lumen anorectal balloon catheters were placed in the rectum and anal sphincter. Special care were taken to ensure that the location of the anorectal catheter ports were near 0.5, 5, 10, and 15 cm from the anal verge. The magnetic coil initially was placed near (L3-L4) along the midline, and the initial stimulation parameters were 70% of maximal intensity, 30 Hz frequency, and 2 second stimulation burst. After the initial stimulation, the frequency (15,20, 25,30, and 35 Hz) and intensity (50, 60,70, 80, and 90%) were varied systematically to obtain the frequency-pressure and intensity-pressure response curves.

Each Colonic Transit Study (CTS) lasted 7 days. This began with subjects ingesting 20 radiopaque markers with breakfast on days 1-3. These markers were size 16 French silastic nasogastric tubes cut in segments 3 mm thick. Abdominal radiographs were taken on days 4 and 7. The radiopaque markers were counted in three segments of the large bowel: the right colon, the left colon, and the rectosigmoid colon. The spinal processes and imaginary lines from LS to the left iliac crest and to the pelvic outlet served as landmarks. The mean transit time were calculated.

After the baseline-CTS was performed, the first three subjects received one week of daily magnetic stimulation while the second colonic transit time was being conducted. A Dantec MagPro magnetic stimulator with a 13.4 cm magnetic coil were used. They received two stimulation treatments per day for 7 days; each treatment lasted twenty minutes. In these 20 minutes, the first 10 minutes were devoted for stimulating the lower thoracic nerves by placing the MC at T-9. The second 10 minutes were used for stimulating the lumbosacral nerves by placing the MC at L4. The stimulation intensities used in these preliminary study subjects varied; subject 1 received stimuli gradually increased from 40-60% intensities, subject 2 received stimuli increased from 45-65% intensities, and subject 3 received stimuli varied from 50-70% intensities. The stimulation frequency, stimulation burst length, and interburst intervals were fixed at 20 Hz, 2 seconds, and 28 seconds, respectively.

Based upon the results obtained from the preliminary study, a standardized magnetic stimulation protocol was adopted. After the baseline-CTS was completed, each subject

underwent a 4-week conditioning period, and this was followed by another week of stimulation while they underwent the stimulation-CTS. This four-week conditioning protocol was consisted of stimulation intensities gradually increased from 40 to 45% in week 1, from 45 to 50 % in week 2, from 50 to 55% in week 3, and from 55 to 60% in week 4. The stimulation intensity used for the final week of stimulation was 60%. Similar to the preliminary stimulation protocol, each subject received two stimulation treatments per day for 7 days; each treatment lasted twenty minutes, including 10 minutes of lower thoracic and 10 minutes of lumbosacral stimulation.

Prior to the Functional Magnetic Stimulation of the bowel, the following data will be obtained: (1) pre-stimulation laboratory results, (2) history and physical examination including demographics, such as type of injury, type of diet, and bowel management, (3) bulbocavernosus reflex latency,(4) rectal inhibitory reflex and (5) anorectal manometry. These data are important in providing the background information, health status of the patient, and the functional type of bladder/bowel patient has. The pre-stimulation laboratory results will be used to compare with the post stimulation laboratory results, in determining whether there is any adverse systemic effect as the result of Functional Magnetic Stimulation from the level of injury data, patients will be classified into three categories, cervical, high thoracic (T1 -TS) and low thoracic (T6-T 10).

From the anorectal manometry data, patients will be divided into two categories, reflexic (anus relaxes at less than 500 ml of rectal filling), or hyporeflexic (without anal relaxation at or greater than 500 ml of fluid filling). Similarly, they will be grouped into various categories based upon the duration of injury (by decade), and the type of bladder/bowel management, and whether they had sphincterotomy. Summary statistics (mean and standard error of the mean) will be performed on the following data: (1) bulbocavernosus reflex latency, (2) the duration of injury, (3) length of an averaged bowel program (in minutes), (4) rectal capacity prior to anal relaxation.

In each case improved colonic transit time in the patient is observed.

EXAMPLE IV

The following is an example of reducing colonic transit time in mammals. The reduction of colonic transit time reduces the likelihood of bowel blockage and the harmful or fatal results from such blockage.

Twenty-four female Wistar rats with weights ranging from 220 - 425 *g* were used. The rats were divided into two groups: experimental and control. In order to control for nonspecific effects on colonic transit time, two rats, one experimental and one control, were handled at the same time. The rats were anesthetized (0.05mg/g Ketamine, 0.0 l mg./mg Xylazine, ip) and a laparotomy was performed to implant a 25 gauge cannula into the cecum.

The cannula was externalized subcutaneously in the interscapular region and the abdominal incision closed. A recovery period of five days was allowed before the start of the experimental protocol on the day of the experiment. 3 ml of Tc-99 (1 μCi/ml} as introduced into the cecum through the cecal catheter. Both experimental and control rats were immediately restrained in plastic sleeves for the remainder of the experiment.

The experimental group had the 9 cm figure-8 magnetic coil (Cadwell Kennewick, WA) placed over the cervical region and functional magnetic stimulation was applied using a magnetic stimulator (high-speed MES-l0; Cadwell, Kennewick, MA). The stimulation parameters were fixed at 40% intensity, 20Hz frequency, and a 5 seconds on/off burst duration for 10 minutes; a 50 minute inter-stimulation interval followed. This cycle of stimulation/rest was performed 4 times. The control group was restrained for the length of the functional magnetic stimulation protocol.

After completion of the functional magnetic stimulation protocol, the rats were euthanized by carbon dioxide asphyxiation. A laparotomy was performed to remove the GI tract; the large intestine was anatomized into 10 segments. The stool was collected and analyzed as an additional segment of the large bowel. The assessment of colonic transit time

was performed by determining the geometric center (GC) of the distribution of radioactivity along the colon.

The rats subjected to the functional magnetic stimulation showed reduced colonic transit time over the segments of the intestine when compared to the rats not subjected to the functional magnetic stimulation.

WHAT IS CLAIMED IS:

1. A method for treating a mammalian subject to reduce colonic transit time thereby regulating the excretory function including the steps of exposing the subject to sufficient electro-magnetic induction for a sufficient period of time to reduce colonic transit time and to induce the excretory function.

2. The method of claim 1 wherein the mammalian subject is human.

3. The method of claim 1 wherein the mammalian subject is exposed to a pulsed electro-magnetic induction where the field strength of the induction is between 1 and 150 Hertz.

4. The method of claim 1 wherein the focus of the electromagnetic induction at that portion of the anatomy of the mammalian subject selected from the group consisting of the T9-10, T11-12, L1-2, L3-4, and the L5-S1 regions.

5. The method of claim 1 wherein the electro-magnetic induction is employed in cycles of 0.5 to 30 seconds.

6. The method of claim 1 wherein more than one electro-magnetic induction is employed per single excretory function.

7. The method of claim 1 wherein the focus of the electromagnetic induction includes that portion of the anatomy of the mammalian subject between the L 4 and S 3 vertebrae.

8. The method of claim 1 wherein the total number of the electro-magnetic induction cycles is from 2 to 300.

9. The method of claim 1 wherein the field strength maximum is less than 3.0 Tesla.

10. The method of claim 11 wherein more than one electro-magnetic induction is employed per single excretory function with an interval between the electro-magnetic inductions from 0.5 to 20 seconds.

11. A method for treating a mammalian subject to regulate the bowel function including the steps of exposing the subject to sufficient electro-magnetic induction for a sufficient period of time to reduce the colonic transit time and to induce the bowel function wherein the field strength maximum of the electro-magnetic induction is less than 5.0 Tesla, and having a focus of the electro-magnetic induction including that portion of the anatomy of the mammalian subject between the L 1 and S 5 vertebrae.

12. A method for treating a mammalian subject to reduce colonic transit time including the steps of exposing the subject to sufficient electro-magnetic induction for a sufficient period of time to reduce colonic transit time.

13. A method for treating a mammalian subject to regulate the excretory function including the steps of exposing the subject to sufficient electro-magnetic induction for a sufficient period of time to induce the excretory function.

14. The method of claim 15 wherein the excretory function is the defecation function.

15. The method of claim 15 wherein the mammalian subject is human.

16. The method of claim 15 wherein the mammalian subject is exposed to a field strength between 1 Hertz and 150 Hertz in the region below the navel and above the buttocks.

17. The method of claim 15 wherein the electro-magnetic induction is employed in cycles of 0.5 to 30 seconds.

18. The method of claim 15 wherein more than one electro-magnetic induction is employed per single excretory function.

19. The method of claim 15 wherein the focus of the electromagnetic induction includes that portion of the anatomy of the mammalian subject between the L 4 and S 3 vertebrae.

20. The method of claim 14 wherein the field strength maximum is less than 3.0 Tesla.

21. The method of claim 14 wherein more than one electro-magnetic induction is employed per single excretory function with an interval between the electro-magnetic inductions from 0.5 to 20 seconds.

22. A method for treating a mammalian subject to reduce gastrointestinal transit time thereby regulating the bowel function including the steps of exposing the subject to sufficient electro-magnetic induction for a sufficient period of time to reduce gastrointestinal transit time and to induce the excretory function.

23. The method of claim 22 wherein more than one electro-magnetic induction is employed per single bowel function with an interval between the electro-magnetic inductions from 5 seconds to 60 seconds and the duration of each electro-magnetic induction is from 5 seconds to 60 seconds.

24. The method of claim 22 wherein the mammalian subject is human.

25. The method of claim 22 wherein the total number of the electro-magnetic induction cycles is from 2 to 300.

ABSTRACT OF THE INVENTION

This invention deals with inducing urination and/or defecation as well as gastrointestinal transit time through electro-magnetic induction. The claimed method provides a non-invasive procedure to stimulate excretory functions in paraplegic and quadriplegic patients.

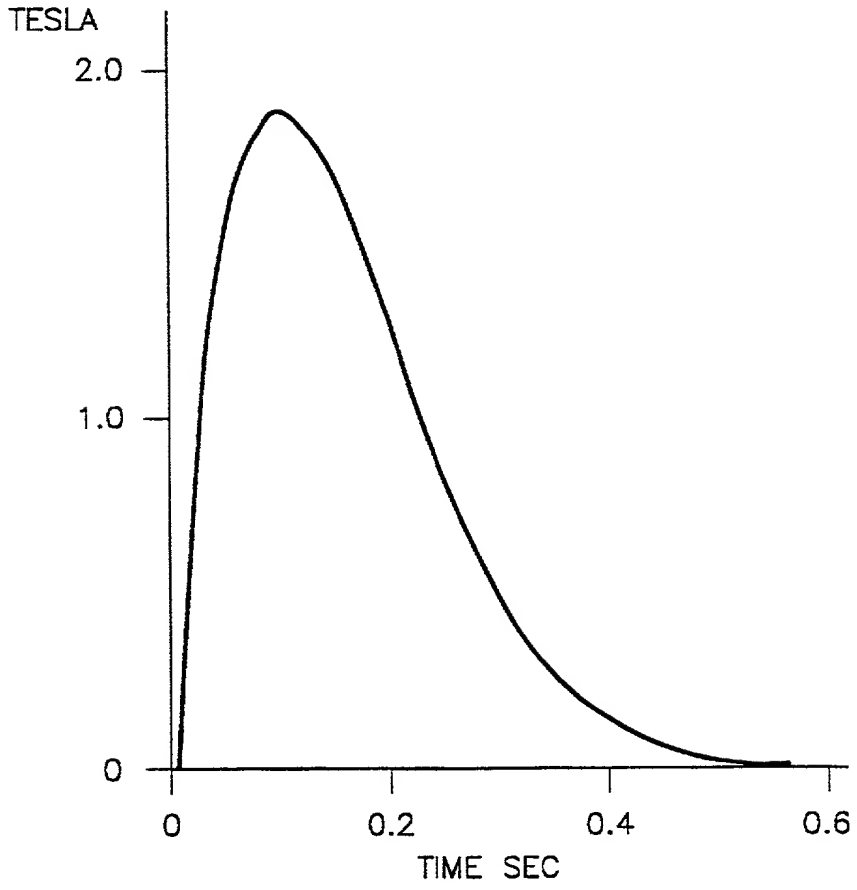


Fig.1

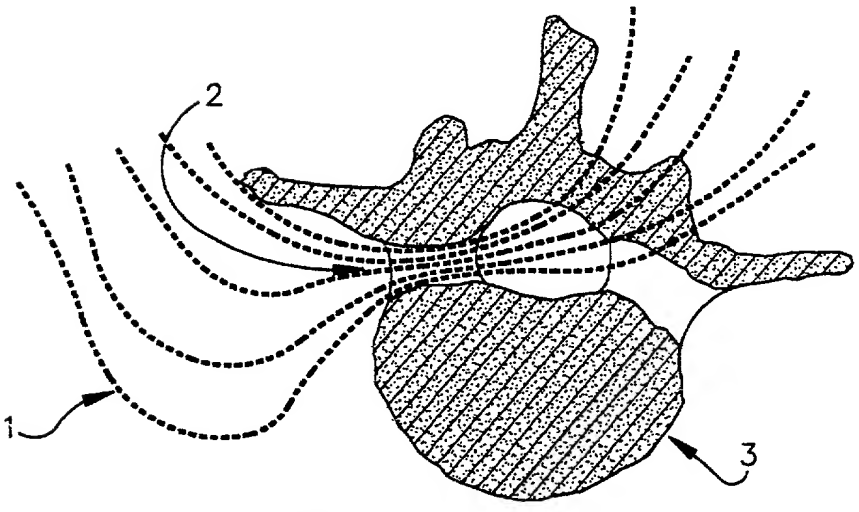


Fig.2

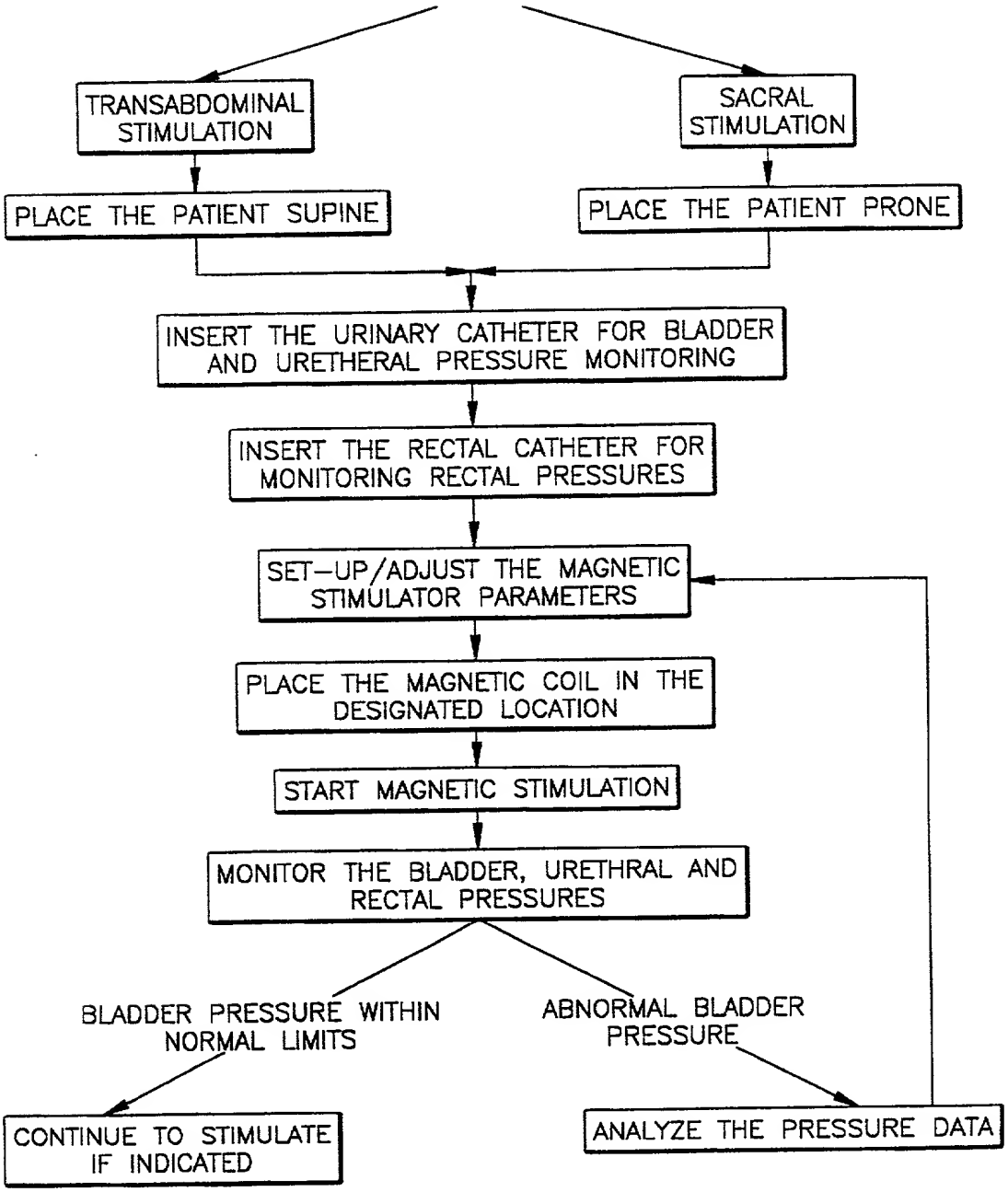
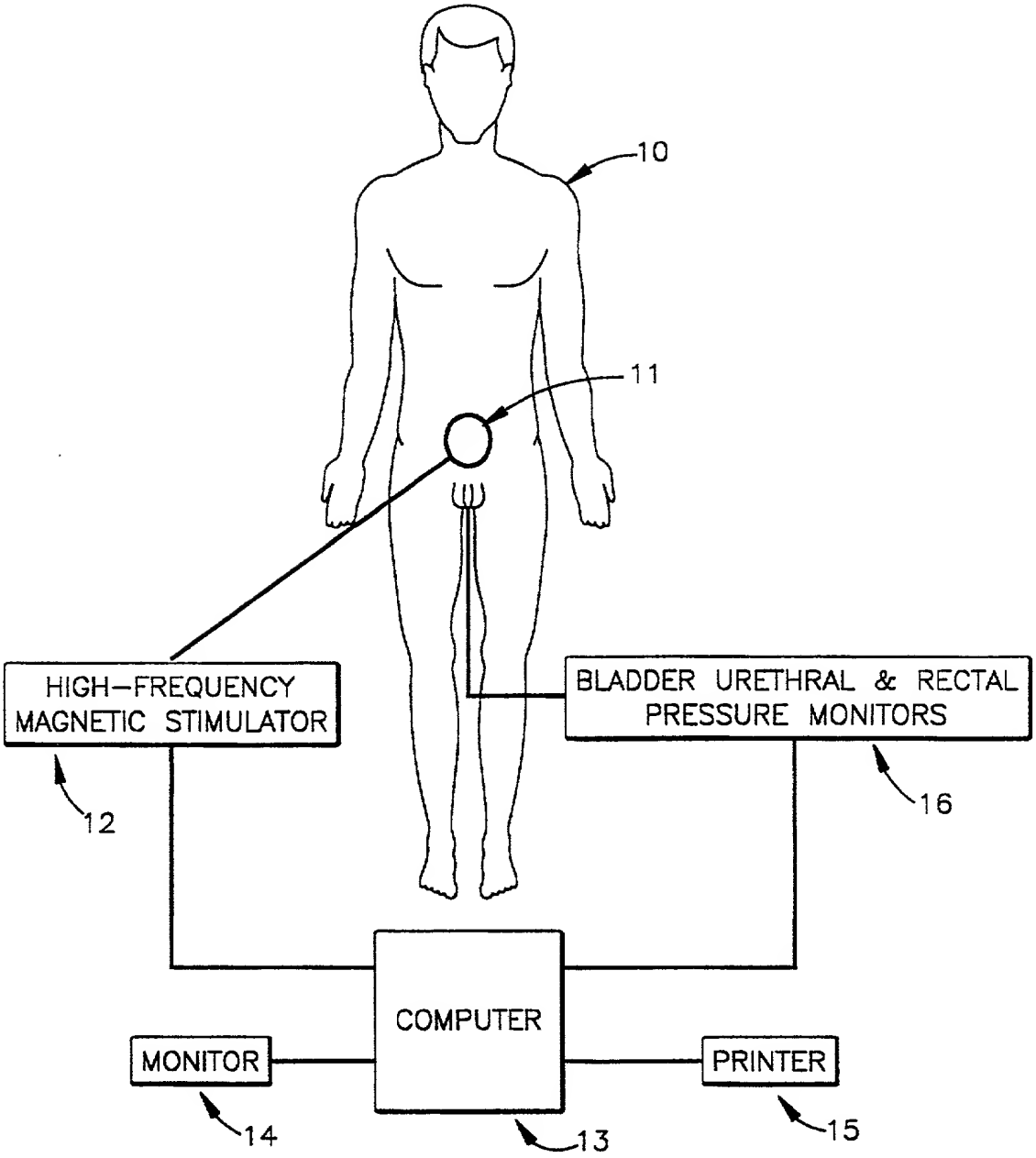

TRANSABDOMINAL STIMULATION
SACRAL STIMULATION
PLACE THE PATIENT SUPINE
PLACE THE PATIENT PRONE
INSERT THE URINARY CATHETER FOR BLADDER AND URETHERAL PRESSURE MONITORING
INSERT THE RECTAL CATHETER FOR MONITORING RECTAL PRESSURES
SET-UP/ADJUST THE MAGNETIC STIMULATOR PARAMETERS
PLACE THE MAGNETIC COIL IN THE DESIGNATED LOCATION
START MAGNETIC STIMULATION
MONITOR THE BLADDER, URETHRAL AND RECTAL PRESSURES
BLADDER PRESSURE WITHIN NORMAL LIMITS
ABNORMAL BLADDER PRESSURE
CONTINUE TO STIMULATE IF INDICATED
ANALYZE THE PRESSURE DATA

Fig.3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11
HIGH–FREQUENCY MAGNETIC STIMULATOR
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BLADDER URETHRAL & RECTAL PRESSURE MONITORS
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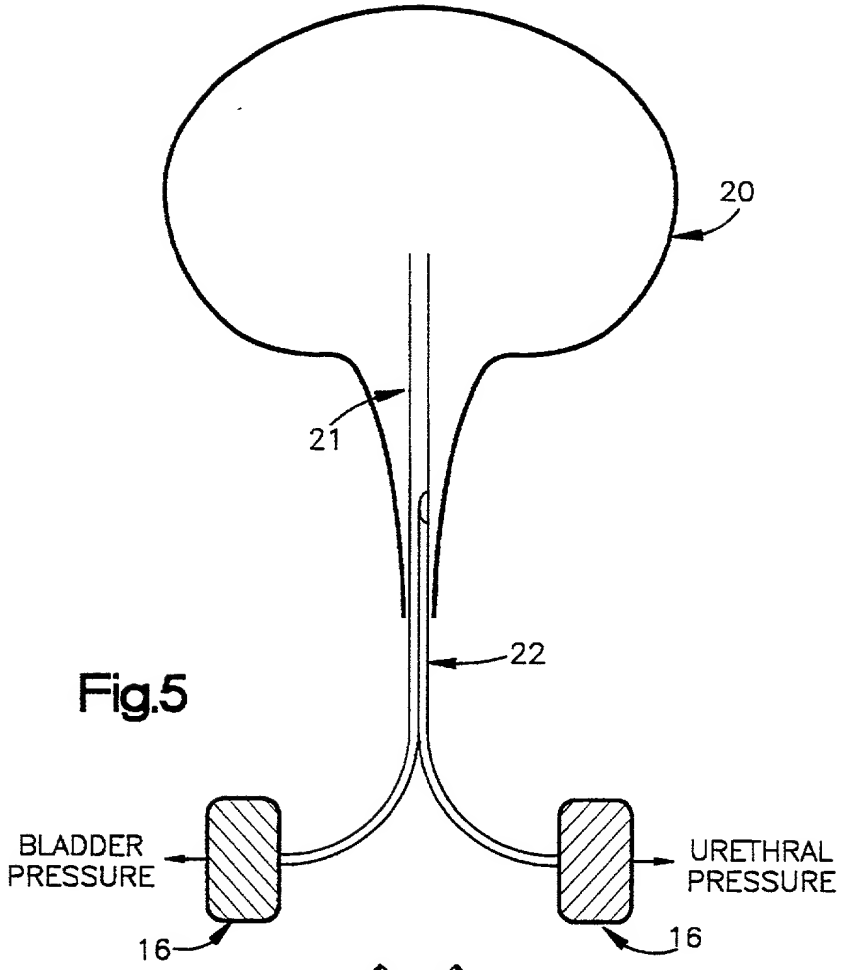
COMPUTER
MONITOR
14
13
PRINTER
15

Fig.4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BLADDER PRESSURE
URETHRAL PRESSURE
16
16

Fig.5

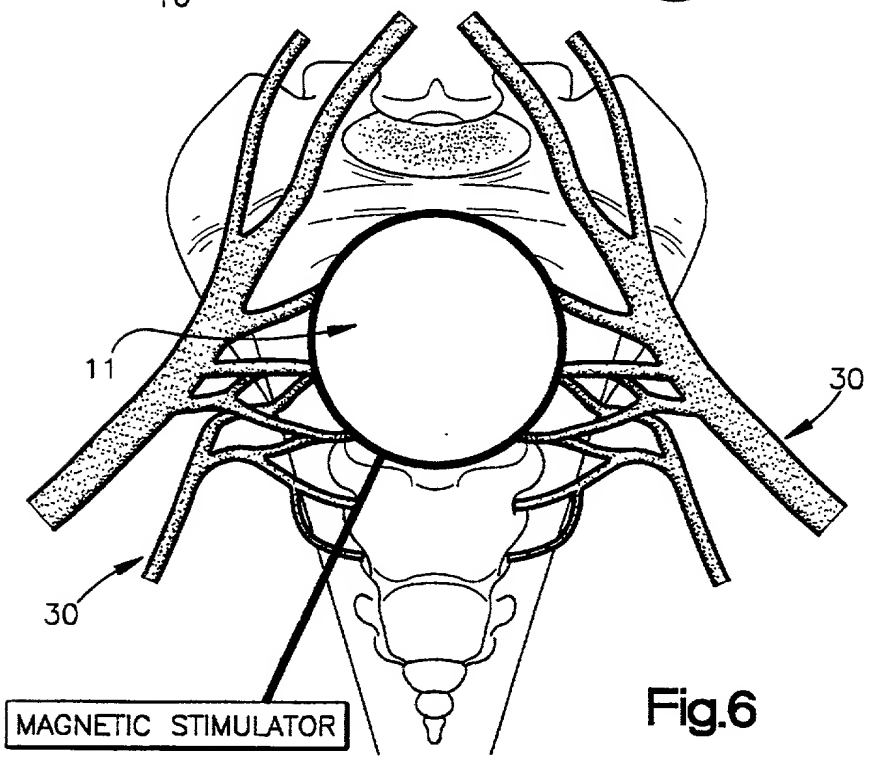
11
30
30
MAGNETIC STIMULATOR

Fig.6

Attorney's Docket No. 1067 *PATENT*

ORIGINAL COMBINED DECLARATION AND POWER OF ATTORNEY

My residence, post office address and citizenship are as stated below next to my name. I believe I am the original, first and sole inventor are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

TITLE OF INVENTION: TREATMENT OF EXCRETORY PROBLEMS

(a) The specification of which is attached hereto.

(b) was filed on as Serial No. and was amended on _____ *(if applicable).*

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37, CODE OF FEDERAL REGULATIONS, § 1.56.

POWER OF ATTORNEY

I hereby appoint the following attorney to prosecute this application and transact all business in the Patent and Trademark Office connected therewith:

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DECLARATION

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under SECTION 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

SIGNATURE(S): _____

Full name of sole or first inventor DR. VERNON WEN-HAU LIN, M.D.

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[X] This declaration ends with this page